Puerto Rico Clinical and Translational Research Consortium

ClinicalTrials.gov

I. Procedure Title: Registration of Clinical Trials on ClinicalTrials.gov

II. Overview/Procedure Description:
This Standard Operating Procedure (SOP) will provide instructions and promote consistency among all investigators at the Puerto Rico Clinical Trial Research Consortium (PRCTRC) regarding the requirements of registering applicable clinical trials with ClinicalTrials.gov. The United States Food and Drug Administration (FDA) is the government agency that requires registration of clinical trials.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) passed on September 27, 2007 a mandatory registration and results reporting for certain clinical trials of drugs, biologics and devices.

As of 2005, most medical journals including The International Committee of Medical Journal Editors (ICMJE) member journals require, as a condition of consideration for publication in their journals, registration in a public trials registry. The ICMJE does not advocate one particular registry, but its member journals require authors to register their trial in a registry that meets several criteria. ClinicalTrials.gov meets these requirements.

According to the FDA and NIH (Food and Drug Administration Amendments Act of 2007): Penalties may include civil monetary penalties up to $10,000 fine for failing to submit or for submitting fraudulent information to ClinicalTrials.gov. After notification of noncompliance, the fine may go up to $10,000 per day until resolved. For federally funded grants, penalties may include the withholding or recovery of grant funds.

For more information about this law and requirements for sponsors and/or investigators, visit the PRS (Protocol Registration System) and U.S. Public Law 110-85 Information Page

A. Purpose:
Outlines the process for registering clinical research studies through the National Institutes of Health website database, www.clinicaltrials.gov

III. Area(s) of Responsibility: Principal Investigator, Regulatory Knowledge and Support Core (RKS), Administrative Core (AC).

IV. Procedure Details:
All applicable clinical trials must be registered in ClinicalTrials.gov. And must be registered no later than 21 days after enrollment of the first participant. Failure to register applicable clinical trails could delay Institutional Review Board (IRB) continuing review approvals for protocols. In addition, failure to register applicable trials by an investigator could delay future research approvals.

The ICMJE clinical trial registration policy requires prospective registration (i.e., registration prior to first person enrolled) of all interventional clinical studies.

Registering Your Study

1. All applicable clinical trials must be registered through the ClinicalTrials.gov Protocol Registration System (PRS). The site is accessible at http://register.clinicaltrials.gov

2. The responsible party is required to register and update the registration record during the course of the trial

    2.1 For investigator-initiated trials, the Overall Principal Investigator (PI) should register each clinical trial affected by the FDAA and ICMJE policy.

    2.2 For trials sponsored of funded wholly or in part by the National Institutes of Health, the Overall Principal Investigator (PI) should contact the sponsor or funding agency to determine registration responsibilities.

    2.3 For trials associated with IND or IDE applications with the FDA, the IND/IDE holder is responsible for registration.

    2.4 If it is unclear who is responsible for registering an applicable clinical trial, the PI should consult with sponsor, funding agency, and/or colleagues to determine whom the responsible party will be.

3. Registration and update requirements include:

    3.1 Registration of the trial on ClinicalTrials.gov

    3.2 **FDA** requires updating information every 12 months

    3.3 **FDA** requires that the registry must be updated within 30 days of any changes in recruitment status or completion of study.

    3.4 **ICMJE** requires updating information every 6 months

    3.5 ClinicalTrials.gov notifies the PI which trials are due for updates

    3.6 Notification to ClinicalTrials.gov within 30 days of study completion.

4. The Overall PI acting as the responsible party should establish accounts and/or gain access to the ClinicalTrials.gov Protocol Registration System (PRS).
5. Trials must be registered after IRB approval but prior to subject enrollment.

V. References:

ClinicalTrials.gov public website - http://clinicaltrials.gov

ClinicalTrials.gov registration site - https://register.clinicaltrials.gov

NIH Guidance on Clinical Trials Registration in ClinicalTrials.gov - http://grants.nih.gov/clinicaltrials_fdaaa/

FACT SHEET - Registration at ClinicalTrials.gov: As required by Public Law 110-85, Title VIII (http://prsinfo.clinicaltrials.gov/)

ICMJE Obligation to Register Clinical Trials - http://www.icmje.org/publishing_10register.html

Learning Module 1: ClinicalTrials.gov Overview and PL 110-85 Requirements - http://prsinfo.clinicaltrials.gov/WebinarSlidesBasicResults.pdf